



Docket No.
452345/0014
JJJ/MCD

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Philip Hougaard
Serial No. : 10/006,601 Group Art Unit: 1614
Filed : December 4, 2001 Examiner: Not Yet Known
For : METHOD OF PLANNING AND PERFORMING
STABILITY STUDIES

March 12, 2002

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, DC 20231

Sir:

Applicant respectfully submits this Information Disclosure Statement pursuant to 37 C.F.R. §§1.97 and 1.98 in order to comply with the duty of disclosure under 37 C.F.R. §1.56. The Examiner's attention is directed to the documents listed on the enclosed Form PTO-1449.

It is respectfully requested that the above information be considered by the Examiner and that a copy of the enclosed Form PTO-1449 be returned indicating that such information has

<p align="center">Certificate of Mailing (37 C.F.R. 1.8)</p> <p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: <i>Commissioner for Patents, Washington, D.C. 20231</i>, on (Date) <u>March 12, 2002</u></p> <p>Typed or printed name of person signing this certificate: <u>Beatrice Cahn</u></p> <p>Signature: <u>Beatrice Cahn</u></p>
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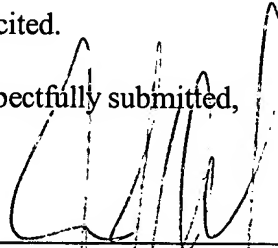
Applicant: Philip Hougaard
U.S. Serial No.: 10/006,601
Filed: December 4, 2001
Page 2

been considered. Applicants respectfully request that the Examiner make these citations of record in the subject application.

This Information Disclosure Statement is being submitted prior to receipt of a first Office Action on the merits. Therefore, no fee is deemed necessary. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 19-4709.

Early and favorable action is earnestly solicited.

Respectfully submitted,



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FORM PTO 1449 (modified)				ATTY DOCKET NO. 452345/0014		APPLICATION NO. 10/006,601	
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary)				APPLICANT Philip Hougaard			
				FILING DATE December 4, 2001		GROUP 1614	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		6,174,856 B1	Jan. 16, 2001	Langballe et al.	514/4		
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES/NO/ OR ABSTRACT
OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)							
		Allen, Paul V. et al. <i>Determination of Release Limits: A General Methodology</i> , PHARMACEUTICAL RESEARCH. Vol. 8, No. 9 (1991) pp. 1210-1213.					
		<i>Shein-Chung Chow et al. Statistical Design And Analysis In Pharmaceutical Science: Validation, Process Controls, And Stability</i> , pp. 5-21, 41-56 (New York: Marcel Dekker, Inc.).					
		Chen, James J.; Hwang, Jing-Shiang; Tsong, Yi: <i>Estimation Of The Shelf-Life Of Drugs With Mixed Effects Models</i> , JOURNAL OF BIOPHARMACEUTICAL STATISTICS 5(1) (1995), pp. 131-140.					
		Wang, Wei: <i>Instability, Stabilization, And Formulation Of Liquid Protein Pharmaceuticals</i> , INTERNATIONAL JOURNAL OF PHARMACEUTICS. 185 (1999) pp. 129-188.					
EXAMINER				DATE CONSIDERED			

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.

Include copy of this form with next communication to applicant.

Sheet 1 of 1